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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/715,927	11/17/2000	Leonard I. Zon	1242.1035-002	6132

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EXAMINER

WEGERT, SANDRA L

ART UNIT

PAPER NUMBER

1647

DATE MAILED: 01/14/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/715,927

Applicant(s)

ZON ET AL.

Examiner

Sandra Wegert

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 August 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-133 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-133 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: |

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-72, drawn to nucleic acids encoding a transporter polypeptide, complementary nucleic acids, vectors, host cells, and methods of producing polypeptides recombinantly, classified in class 435, subclass 69.1+.
- II. Claims 73-102, drawn to a transporter protein, classified in class 530, subclass 350+.
- III. Claim 103-109, drawn to an antibody against a transporter protein and methods of producing an antibody, classified in class 536, subclass 23.5.
- IV. Claims 110-119, drawn to a method of detecting a modulator or ligand of a transporter in isolated membrane assays, classification dependent upon structure of recited compound.
- V. Claims 120-121 and 128, drawn to a method of identifying an inhibitor of iron export in cell culture, classification dependent upon structure of recited compound.
- VI. Claim 122, drawn to an inhibitor of iron export, classification dependent upon structure of recited compound.
- VII. Claim 123, drawn to a method of identifying an inhibitor of iron export in vivo, classification dependent upon structure of recited compound.
- VIII. Claim 124, drawn to an inhibitor of iron export, classification dependent upon structure of recited compound.

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- IX. Claims 125 and 129, drawn to a method of identifying an enhancer of iron export in cell culture, classification dependent upon structure of recited compound.
- X. Claim 126, drawn to an enhancer of iron export, classification dependent upon structure of recited compound.
- XI. Claims 127 and 130, drawn to a method of identifying an enhancer of iron export in vivo, classification dependent upon structure of recited compound.
- XII. Claim 130, drawn to an enhancer of iron export, classification dependent upon structure of recited compound.
- XIII. Claims 131-133, drawn to a method of treating a disease by administering a ligand, classification dependent upon structure of recited compound.

Furthermore, applicant is required to elect one of the following groups a)-f):

- a) SEQ ID NO: 1,
- b) SEQ ID NO: 3,
- c) SEQ ID NO: **5 and 7**,
- d) SEQ ID NO: 2,
- e) SEQ ID NO: 4, or
- f) SEQ ID NO: 6.

SEQ ID NOs: 1, 3, 5 and 7 are drawn to polynucleotides. SEQ ID NO: 2, 4 and 6 are polypeptides.

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The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for Inventive Groups that are directed to different products, restriction is deemed to be proper because these products constitute patentably distinct inventions for the following reasons: Groups I, II and III are independent and distinct, each from the other, because they are products which possess characteristic differences in structure and function and each has an independent utility that is distinct for each invention which cannot be exchanged. The protein of Group II can be used other than to make the antibody of Group III, such as used as a probe, or used therapeutically. The nucleic acid of group I can be used in gene therapy as well as in the production of the protein of interest.

Furthermore, Inventive Groups I and II are related as process of making and product made. The Inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product, or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05 (f)). In the instant case the polypeptide can be prepared by materially different processes, such as by chemical synthesis, or obtained from nature using various isolation and purification protocols.

Invention I is unrelated to inventions IV, V, VII, IX, XI, XIII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects (MPEP §

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806.04, MPEP § 808.01). In the instant case the nucleic acid of Group I is neither used in nor produced by the methods in inventions IV, V, VII, IX, XI, XIII.

Groups VI, VIII, X, and XII are independent and distinct, each from the other, as well as distinct from Groups I-III, because they are products which presumably possess characteristic differences in structure and function and each has an independent utility that is distinct for each invention which cannot be exchanged.

Invention II is related to Invention IV as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05 (h)). In the instant case the polypeptide of Group II can be used therapeutically.

Invention II is related to inventions V, VII, IX and XI as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05 (h)). In the instant case, the polypeptide of Group II can be used other than to search for ligands, such as to make the antibody of group III.

Invention II is unrelated to invention XIII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the polypeptide of Group II is neither used in nor produced by the method of treating a disease by administering a ligand.

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The methods of Inventions I, III, IV, V, VII, IX, XI and XIII are independent and distinct, each from the other, because the methods are practiced with materially different process steps for materially different purposes and each method requires a non-coextensive search because of different starting materials, process steps and goals. Furthermore, Inventions IV, V, VII, IX and XI are related to Inventions VI, VIII, X and XII as a process of detecting a compound and the product detected. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to find other and materially different product or (2) that the product as claimed can be detected by another and materially different process (MPEP § 806.05(f)). In the instant case a ligand of the transporter could be identified by chemical modification and testing of structurally related compounds.

Invention XIII and Inventions VI, VIII, X and XII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05 (h)). In the instant case the ligands of VI, VIII, X and XII can be used other than therapeutically, such as to measure flux across an artificial membrane.

Furthermore, each set of sequences (a) – (f) represents a patentably distinct invention. Groups (a) through (f) are independent and distinct, each from the other, because they have different putative functions, different structures, and require completely different search terms, starting points and strategies.

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Because these inventions are distinct for the reasons given above and the search required for each group is unique, and because each protein or nucleic acid of Groups (a)-(f) requires a completely separate search, as well as by their different classifications, divergent subject matter and different search requirements, restriction for examination purposes as indicated is proper.

In response to this requirement, applicants must elect from Inventive Groups I through XIII, and must additionally elect from Groups (a) - (f). Applicant is advised that in order for the reply to this requirement to be complete it must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R. 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(i).

Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Wegert whose telephone number is (703) 308-9346. The examiner can normally be reached Monday - Friday from 8:30 AM to 5:00 PM (Eastern Time). If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached at (703) 308-4623.

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Official papers filed by fax should be directed to (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

SLW

Elizabeth C. Semone

January 7, 2002

ELIZABETH C. SEMONE
PRIMARY EXAMINER